Message

From: Mendelsohn, Mike [Mendelsohn.Mike@epa.gov]
Sent: 3/23/2020 12:20:57 PM
To: Bohnenblust, Eric [Bohnenblust.Eric@epa.gov]
CC: Reynolds, Alan [Reynolds.Alan@epa.gov]
Subject: RE: 75-day letter
Attachments: EPA-HQ-OPP-2015-0374-0021 Wolbachia HH Risk Assessment wAlBb.pdf

Got it. Thanks.

Here is the info from the wA1Bb EUP amendment.

Assays of wAlbB infected Ae. aegypti are done using Vector Test Systems, Inc. test kits, see Table 1 below. Test are also performed monthly during planned releases to monitor for pathogenic viruses, which will be submitted in Annual EUP reports as the registrant has done previously in 2013 and 2014.

For our call with Oxitec, I suggest the following response to Oxitec's question below in line with your earlier suggestion.

Oxitec Question → "One question I have in advance of Monday's discussion is regarding the arbovirus testing – we put in our EUP application the same testing method (commercial kits) as was used by MosquitoMate for the ZAP Aedes albopictus mosquitoes. I'm curious to know why we need to shift to RT-PCR based testing when these kits have been approved for use in the ZAP mosquitoes – would be helpful to understand! "

Ex. 5 Deliberative Process (DP)

From: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>
Sent: Monday, March 23, 2020 7:54 AM
To: Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Cc: Reynolds, Alan <Reynolds.Alan@epa.gov>
Subject: RE: 75-day letter

Grammatically the way that sentence is written is that the RT PCR method is for Zika which is how I understand their testing to be; PCR for zika and the vector test for the others.

So I don't see anything that refutes that here, I'd have to go back to the MRID or maybe the decision memo.

Eric Bohnenblust, Ph.D
Senior Biologist
Emerging Technologies Branch (ETB)
Biopesticides and Pollution Prevention Division (BPPD)
Phone: 703-347-0426
Email: Bohnenblust.eric@epa.gov

From: Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Sent: Monday, March 23, 2020 7:48 AM
To: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>

Cc: Reynolds, Alan <Reynolds.Alan@epa.gov>
Subject: RE: 75-day letter

Here is the review for the ZAP strain in albopictus supporting registration. We note they are doing PCR.

MosquitoMate has described that mosquitoes are fed blood from cattle at a USDA inspected slaughterhouse. MosquitoMate has described the viruses that can be found in cow's blood including the arbovirus vesicular stomatitis. MosquitoMate will test the cattle blood for the presence of vesicular stomatitis virus three times per year using an assay kit. In addition to the kit. animals are inspected for symptoms of vesicular stomatitis before being slaughtered as a part of routine animal inspections done by USDA inspectors at slaughterhouses. In affected livestock, the incubation period for vesicular stomatitis is from 2 to 8 days. Increased salivation is the first sign of the disease. Close examination of the mouth initially reveals blanched and raised vesicles or blisterlike lesions on the inner surfaces of the lips, gums, tongue, and upper and lower parts of the mouth. The disease can be acquired by mosquitoes by feeding on tainted cow's blood and is transmissible to people, but this has only happened in rare instances (USDA-APHIS, 2012). EPA had also previously asked MosquitoMate to test mosquitoes reared in their facility for certain arboviruses known to be transmittable by Aedes albopiclus, such as Dengue (1,2,3.4 viruses). West Nile Virus. St. Louis Encephalitis virus, Eastern Equine encephalitis, and the Zika virus. MosquitoMate is now testing their ZAP colonies for all these viruses including a test for Zika using a RT-PCR kit.

From: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>
Sent: Monday, March 23, 2020 7:28 AM
To: Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Cc: Reynolds, Alan <Reynolds.Alan@epa.gov>
Subject: RE: 75-day letter

I believe it is part of the manufacturing process. It

Ex. 5 Deliberative Process (DP)

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Eric Bohnenblust, Ph.D
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From: Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Sent: Monday, March 23, 2020 7:25 AM
To: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>
Cc: Reynolds, Alan <Reynolds.Alan@epa.gov>
Subject: RE: 75-day letter

Is the Wolbachia testing method public?

From: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>
Sent: Monday, March 23, 2020 7:21 AM
To: Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Cc: Reynolds, Alan <Reynolds.Alan@epa.gov>
Subject: RE: 75-day letter

I'm going to send an email to everyone but we need to make sure everyone remembers we can't talk about Wolbachia with Oxitec.

Eric Bohnenblust, Ph.D
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From: Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Sent: Friday, March 20, 2020 10:51 AM
To: Nathan Rose <nathan.rose@oxitec.com>; Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>; Keith Matthews <kmatthews@wileyrein.com>
Cc: Reynolds, Alan <Reynolds.Alan@epa.gov>
Subject: RE: 75-day letter

Nathan,

Eric is not working today. Thanks for raising the question on the PCR method. We will address this on Monday's call. I hope all is well with you and Keith at this time. Stay safe.

Best Regards,

Mike Mendelsohn, Chief
Emerging Technologies Branch
Biopesticides and Pollution Prevention Division (7511P)
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1200 Pennsylvania Avenue NW
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(703) 308-8715
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From: Nathan Rose <nathan.rose@oxitec.com>
Sent: Friday, March 20, 2020 8:32 AM
To: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>; Keith Matthews <kmatthews@wileyrein.com>
Cc: Reynolds, Alan <Reynolds.Alan@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Subject: RE: 75-day letter

Hi Eric

Thanks for sending this over – the password works fine and we were able to open it.

One question I have in advance of Monday's discussion is regarding the arbovirus testing – we put in our EUP application the same testing method (commercial kits) as was used by MosquitoMate for the ZAP Aedes albopictus mosquitoes. I'm curious to know why we need to shift to RT-PCR based testing when these kits have been approved for use in the ZAP mosquitoes – would be helpful to understand!

Many thanks,
Nathan

From: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>
Sent: 19 March 2020 19:50
To: Keith Matthews <kmatthews@wileyrein.com>; Nathan Rose <nathan.rose@oxitec.com>
Cc: Reynolds, Alan <Reynolds.Alan@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Subject: 75-day letter

Keith,

Attached is a copy of the 75-day letter. As you are aware, we have a meeting set up for Monday to discuss, but if there are questions in the meantime let me know.

Thanks.

Eric Bohnenblust, Ph.D
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